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10/813,447

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Matthew Baker

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EXAMINER

RYCKMAN, MELISSA K

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/813,447	<b>Applicant(s)</b> BAKER ET AL.	
	<b>Examiner</b> MELISSA RYCKMAN	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 2/27/09.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10-20 and 35-61 is/are pending in the application.
- 4a) Of the above claim(s) 51-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10-14,17-20 and 35-50 is/are rejected.
- 7) ☒ Claim(s) 15 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This office action is in response to claims filed 2/27/09. The applicant's arguments regarding the annular element were persuasive, however the examiner has identified element 208 of Logan to be the annular element, as described in the below rejection.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6,8,10-14, 17, 18, 3 and 46-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Logan et al. (PCT US00/15259).

Regarding Claims 1, 44,46 Logan teaches a connector assembly (200) for use in making an anastomotic connection between an opening prepared at an end of a graft tissue (122) conduit and an aperture in a side wall of a body tissue conduit in a patient comprising: a body disposed annularly about a longitudinal axis and having axially spaced distal and proximal portions, the distal portion having annular element (208) comprising a graft retention component (element with barb attached to 208) to secure the tissue of the graft tissue conduit about the opening to the connector assembly (200),

Art Unit: 3773

and the proximal portion having a plurality of annularly spaced body fingers (204) that expand radially out to engage the interior surface of the side wall of the body tissue conduit about the aperture (Column 7, proximate lines 25-27). The connector assembly further comprises an outside-retention element configured to annularly engage the exterior surface of the graft tissue conduit about the opening (outwardly extending barb portions of retention element 202, fig. 13). The outside-retention element is hingedly coupled to the distal portion of the body (the outside-retention element is made of nitinol, col. 7, ll. 18-34, therefore this is considered hingedly coupled to the distal portion of the body).

Regarding Claims 2 and 39, Logan teaches the connector assembly defined in claims 1 and 35, wherein the graft retention component (202) comprises an annular inside-retention element configured to engage the interior surface of the graft tissue conduit about the opening (fig. 4).

Regarding Claims 3 and 40, Logan teaches the connector assembly defined in claims 2 and 37, wherein the annular inside-retention element (202) has a cross-sectional area larger than the cross-sectional area of the graft tissue conduit (fig. 4).

Regarding Claim 4, Logan teaches the connector assembly defined in claim 2, wherein the annular inside-retention element (202) is unitary with the distal portion of the body (208).

Regarding Claim 5, Logan teaches the connector assembly defined in claim 2, wherein the annular inside-retention element (202) is coupled to the distal portion (208) of the body (Fig. 3).

Regarding Claim 6, Logan teaches the connector assembly defined in claim 2, wherein the annular inside-retention element (202) includes a plurality of annularly spaced inside-retention members that have free ends configured to engage the interior surface of the graft tissue conduit about the opening (fig. 4).

Regarding Claim 8, Logan teaches the connector assembly defined in claim 7, wherein the outside-retention element comprises a plurality of annularly spaced outside-retention members (fig. 13).

Regarding Claim 10, Logan teaches the connector assembly defined in claim 7, wherein the outside-retention element is rigidly connected to the distal portion of the body (fig. 12).

Regarding Claim 11, Logan teaches the connector assembly defined in claim 7, wherein the outside-retention element (outwardly extending barb portions of retention element 202, fig. 13) is slidably coupled to the distal portion of the body (Fig. 13).

Regarding Claim 12, Logan teaches the connector assembly defined in claim 7, wherein the outside-retention element (outwardly extending barb portions of retention element 202, fig. 13) is further configured to engage the exterior surface of the body tissue conduit about the opening (Fig. 13).

Regarding Claim 13, Logan teaches the connector assembly defined in claim 7, wherein the outside-retention element (outwardly extending barb portions of retention element 202, fig. 13) is configured to be at least partially proximal to the plurality of inside-retention members (fig. 13).

Regarding Claim 14, Logan teaches the connector assembly defined in claim 7, wherein the outside-retention element (outwardly extending barb portions of retention element 202, fig. 13) is configured to be at least partially in the same plane as the inside-retention element (fig. 13, a transverse plane).

Regarding Claim 17, Logan teaches the connector assembly defined in claim 1, wherein the radially outward expansion of the plurality of annularly spaced body fingers (204) is an elastic bending (fig. 31).

Regarding Claim 18, Logan teaches the connector assembly defined in claim 1, wherein the body has a medial portion between the proximal portion and the distal portion, wherein the medial portion includes at least one torsional element (206).

Regarding Claim 35, Logan teaches an apparatus for producing the anastomotic connection between the opening prepared at the end of the graft tissue conduit and the aperture in the side wall of the body tissue conduit in the patient comprising: the connector assembly defined in claim 1; and a delivery tool (100) having a first configuration and a second configuration, wherein the first configuration is configured for deforming the proximal portion of the connector assembly from an expanded configuration to a deformed configuration and to advance the deformed proximal portion of the connector assembly into the lumen of the body tissue conduit via the aperture (fig. 15a), and wherein the second configuration is configured for un-deforming the proximal portion of the connector assembly in the lumen of the body tissue conduit (fig. 30).

Art Unit: 3773

Regarding Claim 36, Logan teaches the apparatus defined in claim 35, wherein the loading tool is external to the cannulation of the connector assembly (fig. 5).

Regarding Claim 37, Logan teaches the apparatus defined in claim 35 further comprising a loading tool (134) having a body portion, wherein the body portion is configured to support the distal portion of the connector assembly and to define the resulting shape of the anastomotic connection external to the body tissue conduit (fig. 6).

Regarding Claim 38, Logan teaches the apparatus defined in claim 37, wherein the loading tool further comprises at least one tissue holder (190) configured to engage the exterior surface of the graft tissue conduit about the opening and to hold the graft tissue conduit about the graft retention component of the connector assembly (fig. 12).

Regarding Claims 41 and 47, Logan teaches said annular element has a fixed cross-sectional area (although there is flexibility the cross-sectional area is the same).

Regarding Claim 42, Logan teaches said connector is circular (Fig. 2).

Regarding Claim 43, Logan teaches said graft retention component is connected to the annular element (Fig. 4).

Regarding Claims 48-50, Logan teaches using stainless steel (col. 9, ll. 16,17).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 45 is rejected under 35 U.S.C. 103(a) as being obvious over Logan et al. (PCT US00/15259) as applied to claim 44 above, and further in view of White (U.S. Pub. No. 2004/0093077 A1).

Logan teaches the claimed invention, but does not teach the specific hinge as described in the claim, however White teaches a hinge as claimed. It would have been obvious to one of ordinary skill in the art to use the hinge of White as this would aid in the functionality of the device as the device would be able to be used in a variety of sized tissues and applications.

Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Logan in view of Scholz et al. (US 6273912).

Logan teaches all limitations of preceding dependent claim 1, but fails to teach wherein the opening is prepared by a length-wise axial incision from a toe point at the end of the graft tissue conduit to a heel point along the length of the graft tissue conduit, or wherein the opening is prepared by an incision oblique to the longitudinal axis of the graft tissue conduit from a toe point at the end of the graft tissue conduit to a first point along the length of the graft tissue conduit followed by a length-wise axial incision from



Art Unit: 3773

the first point to a heel point further along the length of the graft tissue conduit. Scholz teaches a graft for end to side anastomosis wherein the opening is formed either by a length-wise axial incision from a toe point at the end of the graft tissue conduit to a heel point along the length of the graft tissue conduit (fig. 4b), or an incision oblique to the longitudinal axis of the graft tissue conduit (fig. 6b) in order to facilitate the anastomosis, increase compliance matching between the graft and the receiving artery, and optimize hemodynamic flow from the graft into the receiving artery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Logan by preparing the opening as taught by Scholz in order to facilitate the anastomosis, increase compliance matching between the graft and the receiving artery, and optimize hemodynamic flow from the graft into the receiving artery.

### ***Allowable Subject Matter***

Claims 15 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's arguments filed 2/27/09 have been fully considered but they are not persuasive. The applicant generally argues the following:

- Logan fails to teach any annular element

Art Unit: 3773

The examiner disagrees with the applicant, element 208 as shown in Figs. 2 and 3 of Logan have an annular shape and are an annular element.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Application/Control Number: 10/813,447

Page 10

Art Unit: 3773

/Melissa Ryckman/  
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773